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Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Additional comments on the HPV Test Plan for 3,6-dichloro-2-trichloromethylpyridine

Dear Administrator Leavitt:

We are writing to express our ongoing concern with Dow AgroSciences LLC's failure to wait for the public comment period before commencing testing under the EPA's HPV program, as is required by the HPV framework agreement to which all participants agreed to adhere. In fact, Dow has repeatedly failed to disclose that testing was already underway in its HPV test plan submissions. In the current instance, Dow's test plan for the chemical 3,6-dichloro-2-trichloromethylpyridine (CAS No. 1817-13-6), did not indicate that animal tests were already being conducted with a surrogate chemical.

Dow's original test plan for 3,6-dichloro-2-trichloromethylpyridine did not propose any animal tests under the HPV program. For this reason, PCRM submitted a letter of support on behalf of the animal protection community. However, after reviewing Dow's revised test plan, posted on October 1, 2004, it appears that Dow has not only violated the principles of the EPA's October 1999 letter of agreement on animal protection, the December 2000 *Federal Register* notice, and the original HPV framework agreement, but has failed to disclose to the public information regarding ongoing animal testing.

Our main concern is the lack of transparency in Dow's original test plan for 3,6-dichloro-2-trichloromethylpyridine, posted on March 8, 2004. Although we support Dow's use of existing data for an analogous chemical, 2,3,4,5,6-pentachloropyridine, to meet the ecotoxicity and some health effects endpoints for 3,6-dichloro-2-trichloromethylpyridine, we were surprised to learn in Dow's revised test plan that a prenatal developmental toxicity study (EPA OPPTS 870.3700) was already being conducted with 2,3,4,5,6-pentachloropyridine. This study was apparently conducted to meet FIFRA requirements and was either planned, or underway, at the same time the original HPV test plan for 3,6-dichloro-2-trichloromethylpyridine was submitted, yet no mention of it was made in the original test plan. It was only after a close examination of the robust summaries in the revised test plan that we became aware of this study (EPA OPPTS 870.3700) and of another separate developmental study (OECD 414) conducted by Dow, just a year later, in 2004, *on the exact same chemical*, 2,3,4,5,6-pentachloropyridine.

After a thorough review of the robust summaries from the revised test plan, we infer that the first developmental study, if conducted in accordance with EPA test guidelines for OPPTS 870.3700, resulted in too few pregnant animals (8 instead of 20). Although Dow provided extensive details on this study, this particular oversight was never clearly stated, though a reference was made to the fact that "pregnancy rate was low due to supplier problems". **Dow then repeated the exact same study, on the exact same chemical, a year later.** We note that the second developmental study included a NOEL for fetotoxicity (absent from the first developmental study) and that the maternal NOEL was reduced by a factor of 5. The second study alone resulted in the death of 1,300 animals and is particularly troublesome in that it clearly demonstrates a complete lack of concern for animal welfare. We would have appreciated an opportunity to comment before the animals were used.

Our second concern is that Dow submitted four separate HPV test plans for four chemicals that belong to the same group—chloropyridines—and all four test plans use existing data for the same surrogate, 2,3,4,5,6-pentachloropyridine, to fill data gaps for SIDS endpoints. These chemicals, all used in the production of chlorinated pesticides, are already regulated under FIFRA and indeed, are subject to numerous animal tests to determine health hazards. We are interested to know if Dow considered grouping these chemicals, as well as the surrogate, into a single category for the purposes of the HPV program and if not, why not.

In summary, we are dismayed with the manner in which Dow withheld information about the ongoing developmental study for the surrogate chemical and then, a year later, repeated the same study, on the same chemical. We would like a response from both Dow and the EPA regarding how they will address these issues in the future.

We had hoped to work together with HPV sponsors, including Dow, to reduce separate and/or duplicative testing. But given the fact that Dow has not been forthcoming regarding ongoing animal studies, efforts at such cooperation become more difficult. Thus, in the future, we do not anticipate writing support letters for Dow's HPV test plans, as we are disappointed by their lack of transparency. If you would like to discuss this matter further, please contact Dr. Chad Sandusky at 202-686-2210 ext. 302 or by email at csandusky@pcrm.org.

Sincerely,

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